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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: REVISED OCCUPATIONAL AND RESIDENTIAL EXPOSURE

ASSESSMENT AND RECOMMENDATIONS FOR THE

REREGISTRATION ELIGIBILITY DOCUMENT FOR DICLOFOP-

METHYL

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Please find attached the occupational and residential exposure assessment for diclofop- methyl

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EXECUTIVE SUMMARY

This is a revision of the original *Occupational and Residential Exposure Assessment and Recommendations Document for Diclofop-methyl*, (S. Tadayon May 30, 2,000). This chapter has been revised to correct for short and intermediate- term inhalation end point. The transfer coefficients (TC) established by Agricultural Reentry Task Force (ARTF) have been used for wheat and barley.

This document contains the occupational exposure assessment for agricultural uses of diclofop-methyl. The document also includes potential risk mitigation measures such as personal protective equipment (PPE) and engineering controls for handlers and proposed restricted entry intervals (REIs) for postapplication activities. The scope of the document covers all diclofop-methyl uses including WPS (Worker Protection Standard) uses for agricultural crops (e.g., wheat and barley, etc.), along with golf course turf uses.

Diclofop-methyl, or methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy] propionate, is a selective post-emergence herbicide, used for the control of wild oats and other annual grasses. The occupational use sites include spring wheat, winter wheat, barley and golf course turf (subject to section 24 authorizations). A wide variety of application techniques have been identified that could potentially be used to apply diclofop-methyl such as fixed -wing- aircraft, tractor-drawn equipment, and hand held equipment. Diclofop-methyl is formulated as a manufacturing product (93.0 percent active ingredient), and **Hoelon® 3EC**, an emulsifiable concentrate liquid (34.7 percent active ingredient).

Acute toxicity categories for the technical grade diclofop-methyl are toxicity category II for oral and dermal, toxicity category IV for inhalation, and toxicity category III for primary eye irritation. Assessment of risk was based on the toxicologic endpoints selected by HIARC. For estimating dermal risk, short- and intermediate-term animal studies reflecting dermal application of the pesticide were used. Both short- term (1-7) days and intermediate-term (7-180)days dermal exposures were compared to a NOAEL of 5 mg/kg/day.

Hazard Identification Assessment Review Committee (HIARC) re-evaluated the available data on August 01, 2000, and selected an endpoint for short and intermediate-term inhalation based on clinical chemistry effects (increased ALT, AST, ALP, malic enzyme and catalase; decreased cholesterol and free fatty acids) and centrilobular hypertrophy in the liver. The NOAEL was established at 20 ppm (**1.6 mg/kg/day**, males; 1.8 mg/kg/day, females) for these risk assessments.

The Carcinogenicity Peer Review Committee met on February 10, 1993 to discuss and evaluate the weight-of evidence on diclofop-methyl with particular reference to its carcinogenic potential. The Committee agreed that diclofop-methyl should be classified as **Group C** (**possible human carcinogen**). The Committee further recommended that for the purpose of risk characterization, a low-dose extrapolation model be applied to the experimental animal tumor data in the mouse. A $\mathbf{Q_1}^*$ of $\mathbf{2.3} \times \mathbf{10^{-1}}$ ($\mathbf{mg/kg/day}$)⁻¹ should be used for human risk assessment.

The Carcinogenicity Peer Review Committee met again on January 5, 2000 to discuss the

combined chronic toxicity/carcinogenicity study in the rat. The committee decided to leave the Q_1 * of 2.3 x 10^{-1} (mg/kg/day)⁻¹ unchanged.

Current HED policy is to assume the exposure duration for short-term assessments to be 1 to 7 days and the duration of intermediate-term exposure to be 7 days to several months. Although information is not available to determine what percentage of applicators apply diclofopmethyl for more than 7 days, it is reasonable to believe that uses of diclofop-methyl by commercial operators may encompass an intermediate-term duration. No chronic (i.e., more than 180 days per year) agricultural uses have been identified.

No **handler** exposure studies were conducted by the registrant, therefore surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, were used to assess the potential exposures resulting from handling and applying diclofop-methyl. Potential exposures and internal doses were calculated using unit exposures (i.e., normalized to amount of active ingredient handled - mg/lb ai handled). The amount of diclofop-methyl assumed handled per day was derived from the application rate and the number of acres that could be applied in a single day. Dermal and inhalation margins of exposure (MOEs) are presented.

A Total MOE is also calculated because there is a common endpoint. The uncertainty factor of 100 is applied to all routes and exposure durations.

The results of the **short and intermediate-term** exposure duration indicate that the total MOEs range from less than 1 to 2615. A total of 13 MOEs were calculated for the various application rates assessed in each scenario. After employing various levels of PPE or engineering controls, all MOEs are estimated to be greater than 100.

The results of the handler **Cancer Risk** indicate that the values range from 1.40E-2 to 5.10E-6 at the baseline, 8.40E-5 to 6.00E-7 with PPE and 5.8E-5 to 1.4E-06 with engineering control.

The Pesticide Handler Exposure Database 1.1 August 1998 (PHED) was used in calculating exposure. The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. The PHED Task Force has evaluated all the data within the system and has developed a set of grading criteria to characterize the quality of the original study data. Mixing/loading liquids and applying liquids by groundboom scenarios have a high quality grade. Mixing/loading liquid for a hand gun sprayer has high quality grade and applying with a hand gun sprayer has low grade. Mixing/loading liquid for fixed-wing aircraft has high quality grade and applying with fixed- wing aircraft has low grade. Flagging for liquid application has high grade.

No **postapplication** exposure studies were conducted by the registrant. Therefore, postapplication exposures to golf course workers and golfers were estimated using assumptions for a surrogate postapplication assessment presented in the Standard Operating Procedures (SOPs) for Residential Exposure Assessments (12/18/1997). The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential SOPs and recommended approaches by HED's Exposure Science Advisory Council (ExpoSAC). The

proposed assumptions are expected to better represent golf course workers and golfers exposure and are still considered to be high-end, screening level assumptions. HED management have authorized the use of the revised residential SOPs that were presented to the FIFRA SAP in September 1999 These data were used in this assessment in conjunction with HED standard values for transfer coefficients to assess potential exposures to workers reentering treated sites. The **results of the occupational postapplication** assessments indicate that entry restrictions for scouting of wheat and barley did not exceed EPA's level of concern provided a 24 hrs REI is observed. For non WPS uses, entry by golf course workers to mow and maintain the turfgrass did not exceed EPA's level of concern on day of application after sprays have dried. In addition, the entry by golfers on the day of application did not exceed EPA's level of concern.

For incidence information two data bases accessed were the Incident Data System (IDS, 1992 to present) and the Poison Control Center data (PCC, 1993-1996). For diclofop-methyl there were 14 cases in IDS and 2 cases in PCC. Of the 2 cases in PCC, one had minor symptoms and the other had symptoms considered to be unrelated to the exposure. Of the 14 IDS cases reported, two may have involved exposure to two or more chemicals so the actual number of cases is probably 10-12, and it would be expected that all were probably minor effects, typically resulting from accidently spraying oneself in the eye or similar type of misuse (Jerry Blondell 4/7/2000).

The handler and postapplication assessments are believed to be reasonable high end representations of Diclofop-methyl uses. There are, however, many uncertainties in these assessments. The uncertainties include but are not limited to the following:

- several generic protection factors were used to calculate handler exposures and these protection factors have not been completely evaluated and accepted by HED;
- not all of the PHED exposure data are of high confidence because of the lack of replicates and/or inadequate QA/QC in the studies;
- no chemical-specific exposure or transferable residue data were submitted and as a result, all analyses were completed using surrogate data from sources such as PHED and assumptions related to the behavior and environmental fate of Diclofop-methyl in the environment (e.g., dissipation of transferable residues);
- factors used to calculate postapplication risks (e.g., hours exposure per day or average reentry day) are often based on the best professional judgment due to a lack of pertinent data.

1.0 BACKGROUND

Purpose

In this document, which is for use in EPA's development of the diclofop-methyl Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to diclofop-methyl.

Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered <u>and</u> (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For diclofop-methyl, both criteria are met.

1.1 Summary of Toxicity Concerns Relating to Occupational Exposures

Acute Toxicology Categories

Table 1 presents the acute toxicity categories as outlined in the HIARC Document (August 01, 2000).¹

Table 1: Acute Toxici	ty Categ	gories for Technical formulation of diclofo	p-methyl	
Study Type	Animal	Results	Tox Cat	MRID No
870-1100 Acute Oral (LD ₅₀)	Rat	Male: 481 mg/kg Female: 500-630 (estimate) mg/kg Combined 512 (428-636) mg/kg	II	41476001 92036052
		Male: 580 mg/kg	II	00123982
		Female: 557 mg/kg	II	00123983
870-1200: Acute Dermal (LD ₅₀)	Rat	Male and Female: > 2000 mg/kg	II	00071522 92036013
870-1300: Acute Inhalation	Rat	IV	00032595	
(LC_{50})		Male and female > 4.75 mg/L	IV	41573304
		Male and female > 3.83 mg/L	IV	00032595
870-2400: Primary Eye Irritation	Rabbit	Slight ocular irritant, Conjunctival redness and discharge at 24 hr, cleared by 72hr	III	42428601
870-2500: Primary Dermal Irritation	Rabbit	Slight irritant, PII = 0.8 (0 to 72 hr)	IV	40213506
870-2600: Dermal Sensitization	Guinea Pig	Buehler: Negative	NA	41476003 92036047
		Maximization: Moderate to severe sensitizer	NA	41476002 41476003 92036046

Other Endpoints of Concern

The Revised Report of the Hazard Identification Assessment Review Committee (HIARC) for diclofop-methyl, dated August 01, 2000 indicates that there are toxicological endpoints of concern for diclofop-methyl. The endpoints used in assessing the risks for diclofop-methyl are presented in Table 2.

Table 2: Endpoints for Assessing Occupational and Residential Risks for Diclofop-methyl¹

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY						
Short-Term (Dermal)	NOAEL = 5 mg/kg/day	Based on increased liver enzymes, proteins, and absolute and relative liver weights.	870.3200 21-Day Dermal Toxicity Study in the Rat						
Intermediate Term (Dermal)	NOAEL = 5 mg/kg/day	Based on increased liver enzymes, proteins, and absolute and relative liver weights.	870.3200 21-Day Dermal Toxicity Study in the Rat						
Long-term Non-cancer (Dermal)		Based on the use pattern (applied at the rate of 454 g ai/acre up to a maximum of 1 pplication/crop cycle), this risk assessment is not required							
Inhalation (Short and Intermediate)	NOAEL = 1.6 mg/kg/day	Based on increased liver enzymes, proteins, and absolute and relative liver weights.	870.3100 Subchronic Oral Toxicity Study in the Rat						
Inhalation (Long-term)		the use pattern (applied at the rate of 454 g ai/acre up to a maximum of 1 on/crop cycle), this risk assessment is not required							
Cancer (Dermal and Inhalation)	Q ₁ * of 2.3 x 10 ⁻¹ (mg/kg/day) ⁻¹	Based on liver adenomas and carcinomas with significant trend and pair-wise comparisons.	870.4200 Mouse Carcinogenicity Study						

A Total MOE is calculated because there is a common endpoint. The uncertainty factor of 100 is applied to all routes and exposure durations. Route specific data are available for the dermal and oral routes, and therefore, the reciprocal MOE calculation is used.

1.2 Summary of Use Patterns and Formulations

At this time products containing diclofop-methyl are intended for occupational use only. Occupational uses include golf course turf, and food crops.

Type of Pesticide/Target Pests

Diclofop-methyl, or methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy] propionate (restricted use), is a selective post-emergence herbicide, used for the control of wild oats and other annual grasses. The occupational use sites include spring wheat, winter wheat, barley, and golf course turf (subject to section 24 authorizations). Diclofop-methyl is applied once a season and is based on weed leaf stage. Less than 1 percent is soil incorporated.

Formulation types and percent active ingredient

Diclofop-methyl is formulated² as a manufacturing product (93.0 percent active ingredient), and **Hoelon**® **3EC**, an emulsifiable concentrate liquids (34.7 percent active ingredient).

1.3 <u>Method and Types of Equipment Used for Mixing/Loading/Applying</u>

The Agency determines potential exposures to pesticides handlers by identifying exposure scenarios from the various application equipment-types that are plausible given the label uses. Based on reviewing pesticide labels and professional judgement, the use patterns specific to diclofop-methyl are associated with the following application equipment:

- Aerial (Spray) Equipment: post emergence application on wheat and barley
- Groundboom Equipment: post emergence application on wheat, barley, and golf courses
- Spot treatment of golf courses with hand gun sprayer

1.4 Incident Reports

BACKGROUND

The following data bases have been consulted for the poisoning incident data on the active ingredient Dicloflop Methyl³:

- 1) OPP Incident Data System (IDS) reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.
- 2) Poison Control Centers as the result of a data purchase by EPA, OPP received Poison Control Center data covering the years 1993 through 1996 for all pesticides. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.
- 3) California Department of Pesticide Regulation California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.
- 4) National Pesticide Telecommunications Network (NPTN) NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

DICLOFLOP METHYL REVIEW

I. <u>Incident Data System</u>

Please note that the following cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted.

Incident#3037-82

A pesticide incident occurred in 1993, when a plane crashed and individuals were exposed to the product. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

Incident#3037-84

A pesticide incident occurred in 1993, when an individual experienced malaise two weeks after application of the product. No further information on the disposition of the case was reported.

Incident#3037-85

A pesticide incident occurred in 1993, when an individual experienced nausea and stomach cramps twelve hours after application of the product. No further information on the disposition of the case was reported.

Incident#3037-87

A pesticide incident occurred in 1993, when an individual experienced nausea during a normal spot treatment with the product. No further information on the disposition of the case was reported.

Incident#3037-92

A pesticide incident occurred in 1993, when an individual experienced rashes and swelling. No further information on the disposition of the case was reported.

Incident#3037-99

A pesticide incident occurred in 1993, when an individual experienced severe chest pain. No further information on the disposition of the case was reported.

Incident#3037-101

A pesticide incident occurred in 1994, when an individual accidentally had the product spilled onto their skin and experienced vomiting and diarrhea. No further information on the disposition of the case was reported.

Incident#3037-139

A pesticide incident occurred in 1995, when a man, who was intoxicated, was licking golf balls on a course that was previously treated with the product. He collapsed and also experienced lethargy. No further information on the disposition of the case was reported.

Incident#3037-140

A pesticide incident occurred in 1995, when a woman experienced respiratory symptoms after a golf course was sprayed with the product. No further information on the disposition of the case

was reported.

Incident#7250-54

A pesticide incident occurred in 1998, when a thirty-eight year old individual ingested the product and experienced chest pain and throat irritation. No further information on the disposition of the case was reported.

Incident#7903-6

A pesticide incident occurred in 1998, when an individual, who was treated by a physician, was exposed to the product after it was blown into their face. They experienced blurred vision in both eyes that progressed to double vision. No further information on the disposition of the case was reported.

II. Poison Control Center Data - 1993 through 1996

Two exposures were reported to diclofop methyl in the Poison Control Center database. Both exposures occurred in adults. One adult reported minor effects and the other experienced effects deemed unrelated to the exposure.

III. <u>California Data - 1982 through 1996</u> - No Data

IV. National Pesticide Telecommunications Network

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, dicloflop methyl was not reported to be involved in human incidents.

VI. Conclusions

Relatively few incidents of illness have been reported due to diclofop methyl.

VII. Recommendations

No recommendations can be made based on the few incident reports available.

2.0 OCCUPATIONAL EXPOSURES

2.1 Handler Exposures & Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with diclofop-methyl. Based on the use patterns and

potential exposures described above, 7 likely exposure scenarios are identified to represent the extent of diclofop-methyl uses.

- (1) Mixing/loading liquids for groundboom application;
- (2) Mixing/loading liquids for aerial application;
- (3) Mixing/loading liquids for hand gun sprayer application;
- (4) Applying liquids with a groundboom sprayer;
- (5) Applying liquids with fixed-wing-Aircraft;
- (6) Applying liquids with hand gun sprayer;
- (7) Flagging for liquids application.

The potential handler exposures to the 7 exposure scenarios are assessed in this RED chapter using the toxicological endpoints and uncertainty factors associated with the active ingredient. Therefore, the PPE and engineering controls are determined by the assessment of the active ingredient and not the currently required risk mitigation measures on diclofop-methyl labels. This distinction of determining risk mitigation measures based on the active ingredient instead of the label required PPE is also important because of the nature of the end-use products. For example, some end-use products require additional PPE that are not necessary for the active ingredient because of the end-use product's potential for eye and/or skin irritation based on inert. Conversely, the Agency does not want to mandate additional PPE (e.g., heat stress issues) if it is not required based on the endpoint and uncertainty factors. There are some PPE, such as chemical-resistant aprons and/or head gear, that the Agency uses as qualitative measures because there are no recognized protection factors (PF) to assess their effectiveness. The Agency's risk managers require these types of PPE as additional mitigation. For example, chemical-resistant aprons are often required to protect mixer/loaders from accidental spills.

In most cases, HED assesses the exposure and risk to mixer/loaders and applicators separately for tractor drawn applications (i.e., groundboom, and granular spreaders) in the RED chapter. This practice has evolved, not because it is believed that there are always separate job functions, but rather because of the limited amount of information regarding these practices along with limited exposure data.

HED has adopted a methodology to present the risks separately for some scenarios and combine others. Most of the hand- held equipment such as backpack sprayers, and push type granular spreaders are assessed as a combined function. These types of small operations the mixing, loading, and applying are almost always carried out by the same individual and there are data available to estimate exposure from these activities. For equipment such as fixed-wing-aircraft, groundboom tractors, and airblast sprayers the applications are assessed separately from the individual who mixes and loads the formulated product. HED assumes that the pilots are rarely involved in the mixing/loading. By separating the two job functions, HED can determine the most appropriate PPE without requiring the handler to wear PPE unnecessarily throughout the entire workday.

2.1.1 Summary of Occupational Handler Exposures

Table 3 presents the exposure scenarios, application rates, and area (i.e., acres) potentially treated that have been used in the exposure calculations.

The calculations for the short-term and intermediate- term occupational assessment are provided in appendix A. However the uses of diclofop-methyl are believed to be better represented for commercial handlers by the intermediate-term (7 days to several months) exposure duration. The results of the short-term and intermediate-term MOEs are presented in a summary table (see Table 4).

Since there were no chemical-specific exposure data to assess the potential handler exposure to diclofop-methyl, PHED V1.1⁴ has been used to assess the exposure scenarios. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. PHED was designed by a Task Force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application

method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing). Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include administrative controls, the use of personal protective equipment or PPE, and the use of engineering controls. Occupational handler exposure assessments are completed by HED using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure or cancer risk. The baseline clothing/PPE ensemble for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical-resistant gloves (there are exceptions pertaining to the use of gloves), and no respirator. The first level of mitigation generally applied is PPE. As reflected in the calculations that follow, PPE may involve the use of an additional layer of clothing, chemical-resistant gloves, and/or a respirator. The next level of mitigation considered in assessing exposure and risk is the use of appropriate engineering controls which, by design, attempt to reduce or eliminate the potential for exposure. Examples of commonly used engineering controls include closed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets. [Note: Administrative controls may include methods such as altering application rates for handler

exposure scenarios.

Table 3: Exposure Variables for Uses of Diclofop-	Methyl	
Exposure Scenario (Scenario #)	Application Rates (lb ai/acre) ^a	Daily Acres Treated ^b
Mixer/L	oader Exposure	
Mixing/loading liquids for groundboom application	1.0 lb ai/acre wheat & barley	80
(1)	min 1.0lb ai/acre golf course	40
	max 1.5 lb ai/acre golf course	
Mixing/loading liquids for aerial application (2)	1.0 lb ai/acre wheat & barley	350
Mixing/loading liquids for hand gun sprayer (3)	min 1.0 lb ai/acre golf course	5
application	max 1.5 lb ai/acre golf course	
A	pplicator	
Applying liquids with a groundboom sprayer (4)	1.0 lb ai/acre wheat & barley	80
	min 1.0lb ai/acre golf course	40
	max 1.5 lb ai/acre golf course	
Applying liquids with fixed-wing-aircraft (5)	1.0 lb ai/acre wheat & barley	350
Applying liquids with hand gun sprayer (6)	min 1.0lb ai/acre golf course	5
	max 1.5 lb ai/acre golf course	
	Flagger	
Flagging for liquid application (7)	1.0 lb ai/acre wheat & barley	350

^aApplication rates are the maximum labeled rates found on EPA Reg.45639-177 AL90001100, AR93000200, FL89003000, FL96000100, GA90000600, GA95000900, LA93000700, LA98000800, MS91001900, NC91000100, OK93000300, SC90000300, TN93000800, TX92000900.

2.1.2 Summary of Uncertainties

The handler exposure assessments encompass all of the major uses of diclofop- methyl throughout the country.

Application Rates: Each exposure scenario includes the allowable maximum application rate that was identified on the available product labels. In addition, a range of application rates was used for golf courses. Other than a national survey, there are no statistical techniques to determine what rates to include in an assessment -- other than always including the maximum rates. In most instances, the maximum

^bDaily acres treated are based on HED's estimates of acreage that would be reasonably expected to be treated in a single day for each exposure scenario of concern.

labeled application rates were applied to application techniques that are feasible given the amount of dilute spray that needs to be applied.

- Amount Handled: The daily acres treated are HED standard values (see Table 3). Deviations from the HED standard values include groundboom acreage for the golf courses. For golf courses assessment, 40 acres was used for groundboom application.
- Unit Exposures: The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. Mixing/loading liquids and applying liquids by groundboom scenarios have a high quality grade. Mixing/loading liquid for a hand gun sprayer has high quality grade and applying with a hand gun sprayer has low grade. Mixing/loading liquid for fixed-wing aircraft has high quality grade and applying with fixed- wing aircraft has low grade. Flagging for liquid application has high grade. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A-Table A4. While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.
- Representativeness of Surrogate Data: The majority of the application techniques from PHED are typical equipment types expected to be used for diclofop-methyl treatments.

2.1.3 Calculations of Exposure

Potential daily dermal exposure is calculated using the following formula:

Daily Dermal Exposure
$$\left(\frac{mg\ AI}{Day}\right)$$
 = Dermal Unit Exposure $\left(\frac{mg\ AI}{lb\ AI}\right)$ · Max. Appl. Rate $\left(\frac{lb\ AI}{Acre}\right)$ · Max. Area Treated $\left(\frac{Acres}{Day}\right)$

Potential daily inhalation exposure is calculated using the following formula:

$$Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right) = \\ Unit\ Exposure\left(\frac{\mu g\ ai}{lb\ ai}\right)\ x\ Conversion\ Factor\left(\frac{1mg}{1,000\ \mu g}\right)\ x\ Use\ Rate\left(\frac{lb\ ai}{A}\right)\ x\ Daily\ Acres\ Treated\left(\frac{A}{day}\right)$$

These calculations of potential daily exposure to diclofop-methyl by handlers are used to calculate the absorbed doses and total risk to those handlers (see *Occupational Risk* section).

2.2 Risk From Handler Exposures

Using the daily dermal exposure scenarios identified in the exposure section, EPA calculated the potential risk to persons from handler exposures and post-application exposures to diclofopmethyl.

Potential dermal and inhalation daily exposures for occupational handlers were calculated using the following formulas:

The inhalation and dermal daily doses were calculated using the following formulas:

Daily Inhalation Dose
$$\left(\frac{mg\ ai}{kg/day}\right) = Daily\ Inhalation\ Exposure \left(\frac{mg\ ai}{day}\right) x \left(\frac{1}{Body\ Weight\ (kg)}\right) *1 (100%)$$

Daily Dermal Dose
$$\left(\frac{mg\ ai}{kg/Day}\right) = Daily\ Dermal\ Exposure \left(\frac{mg\ ai}{Day}\right) \times \left(\frac{1}{Body\ Weight\ (kg)}\right) *1 (100\%)$$

The MOEs were calculated using the following formulas:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Dermal\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Inhlation \ Daily \ Dose\left(\frac{mg}{kg/day}\right)}$$

A total MOE is also calculated because there is a common endpoint. The uncertainty factor of 100 is applied to all routes and exposure durations. Route specific data are available for the dermal and oral routes, and therefore, the following reciprocal MOE calculation is used:

1/((1/Dermal MOE) + (1/Inhalation MOE)

2.2.1 Estimation of Cancer Risk

Cancer risk assessments for handlers were completed by EPA using a baseline exposure scenario and, as needed, increasing levels of risk mitigation (PPE and engineering controls) to achieve cancer risks that are not of concern. Table B in Appendix B presents estimation of cancer risk at baseline, with PPE and with engineering controls, respectively, for each exposure scenario.

The calculations of daily dermal and inhalation exposure to diclofop-methyl by handlers were used to calculate the daily dose, and hence the risks, to those handlers.

Daily Dermal Exposure
$$\left(\frac{mg\ ai}{day}\right)$$
 = Unit Exposure $\left(\frac{mg\ ai}{lb\ ai}\right)$ x Use Rate $\left(\frac{lb\ ai}{A}\right)$ x Daily Acres Treated $\left(\frac{A}{day}\right)$

Potential daily inhalation exposure was calculated using the following formula:

Daily Inhalation Exposure
$$\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure \left(\frac{\mu g\ ai}{lb\ ai}\right) x\ Conversion\ Factor \left(\frac{1mg}{1,000\ \mu g}\right) x\ Use\ Rate \left(\frac{lb\ ai}{A}\right) x\ Daily\ Acres\ Treated \left(\frac{A}{day}\right)$$

The daily dermal and inhalation doses were calculated using a 70 kg body weight using the following formulas:

Daily Dermal Dose
$$\left(\frac{mg\ ai}{Kg/Day}\right) = Daily\ Dermal\ Exposure\ \left(\frac{mg\ ai}{Day}\right)\ x\left(\frac{1}{Body\ Weight\ (Kg)}\right)\ xI\ (15\%)\ Dermal\ Absorption\ Factor$$

$$Daily\ Inhalation\ Dose\left(\frac{mg\ ai}{kg/day}\right)\ =\ Daily\ Inhalation\ Exposure\left(\frac{mg\ ai}{day}\right)\ x\left(\frac{1}{Body\ Weight\ (kg)}\right)$$

Total Daily Dose = Daily Dermal Dose
$$\left(\frac{mg}{kg/day}\right)$$
 + Daily Inhalation Dose $\left(\frac{mg}{kg/day}\right)$

The lifetime average daily dose (LADD) was calculated using the following formula:

$$LADD\left(\frac{mg}{kg/day}\right) = Daily \ Total \ Dose\left(\frac{mg}{kg/day}\right) \ x\left(\frac{days \ worked}{365 \ days \ per \ year}\right) \ x\left(\frac{35 \ years \ worked}{70 \ year \ lifetime}\right)$$

Total cancer risk was calculated using the following formula:

where
$$Q_1^* = 2.3 \times 10^{-1}$$

The following assumptions and factors were used in order to complete this cancer risk assessment:

- The average body weight of 70 kg is used, representing a typical adult.
- Career duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years.

- Dermal absorption is assumed to be 15 percent and inhalation absorption 100 percent. The dermal and inhalation doses were added together to represent total daily dose.
- The Q1* used in the cancer assessment was 2.3x10⁻¹(mg/kg/day)⁻¹.
- Maximum PPE (coveralls and dust/mist respirator) were used for this assessment.
- Two exposure frequencies were used for wheat and barley in the calculations, the first represented the maximum number of applications per site per year to represent private use (10 days), and the second frequency applied a factor of 2 to the first frequency to represent commercial handlers making multiple applications per site per year (20 days) For golf courses 10 days per year.

2.2.2 Non-Cancer Risk Estimates From Handler Exposures

Margins of exposure (MOEs) were calculated for handlers for short-term (one to seven days) and intermediate-term (one week to several months) durations. Appendix A presents the MOE calculations for baseline attire, personal protective equipment (PPE) and engineering control from PHED for uses of diclofop-methyl. Tables A1, A2 and A3, present the short and intermediate-term baseline, PPE and engineering control respectively.

HED calculated the baseline total MOE for each occupational exposure scenario using the following assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots), foot exposure is not traditionally monitored, and therefore, a 100 percent protection factor is implied;
- occupational mixers and loaders using open mixing techniques are wearing longsleeved shirts, long pants and no gloves;

If the baseline total MOE was 100 or greater (the NOAEL is based on data from animal studies, and therefore, a 10x is applied for both inter-species and intra-species variations) for an exposure scenario, then no further calculations were made. If the baseline total MOE remained less than 100 for any occupational exposure scenario, an addition total MOE was calculated based on mandatory use of PPE. HED calculated the PPE total MOE for each occupational exposure scenario with a PPE total MOE of less than 100, using the following <u>PPE</u> assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots), foot exposure is not traditionally monitored, and therefore, a 100 percent protection factor is implied;
- occupational mixers and loaders using open mixing techniques are wearing gloves, long-sleeved shirts and long pants;
- occupational applicators who use open cab groundboom or tractor-driven application equipment and handlers flagging for aerial applications are wearing gloves (except

flaggers -- no gloves) plus coveralls worn over long-sleeved shirts and long pants;

- occupational handlers who use high pressure handwands are wearing gloves plus long-sleeve shirts and long pants.
- Also, if necessary, an organic vapor respirator represented by a 10-fold protection factor is added to mitigate the risks.

If the PPE total MOE remained less than 100 for any occupational exposure scenario, another total MOE was calculated based on mandatory use of engineering controls where feasible. Engineering controls are not available for occupational handlers (mixers, loaders, and applicators) who use hand-held application equipment. HED calculated the engineering-control total MOE for each occupational exposure scenario with a PPE total MOE of less than 100, using the following assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots), foot exposure is not traditionally monitored, and therefore, a 100 percent protection factor is implied;
- occupational mixers and loaders handling liquid formulations using a closed system are wearing chemical-resistant gloves plus long-sleeved shirts and long pants;
- occupational applicators who use aerial, groundoom, or tractor-driven application equipment and handlers flagging for aerial applications are located in enclosed cabs or cockpits and are wearing long-sleeved shirts and long pants, and no gloves.

2.2.3 Summary of MOEs

Table 4 summarizes the numeric total MOE values for both the short- and intermediate-term exposure durations. In the majority of cases, it is dermal exposure rather than the inhalation exposure driving the total MOEs. The MOEs are presented for baseline, PPE and engineering controls as needed. Baseline represents exposure while wearing long pants, long sleeved shirts and PPE represents exposure while wearing long pants, long sleeved shirts and gloves while using open mixing/loading systems and open cab tractors. The engineering controls represent exposure while wearing long pants, long sleeved shirts and no gloves (except chemical resistant gloves for closed loading systems) while using closed mixing/loading systems and enclosed cabs/cockpits.

The results of the **short and intermediate-term** exposure duration indicate that the total MOEs range from less 1 to 2615 representing baseline clothing. A total of 13 MOEs were calculated for the various application rates assessed in each scenario. After employing various levels of PPE or engineering controls, all MOEs are estimated to be greater than 100.

The results of the handler **Cancer Risk** indicate that the values range from 1.40E-2 to 5.10E-6 at the baseline, 8.40E-5 to 6.00E-7 with PPE and 5.8E-5 to 1.40E-6 with engineering control.

Exposure Scenario	Application	Acres	Total S	Short -term 1	МОЕ	Total I	ntermediate-	term MOE		Cancer	
(Scenario #)	Rates (lb ai/A)	Treated per Day	Baseline	PPE	Eng. Control	Baseline	PPE	Eng. Control	Baseline	PPE	Eng. Control
				M	ixer/Loader I	Risk					
Mixing/loading liquids for groundboom application (1)	1.0	80	2	165	NA	2	165	NA	1.60e-03/ 3.20e-03	9.61e-06/ 1.92e-05	4.90e-06/ 9.80e-06
	1.0	40	3	325	NA	3	325	NA	7.90e-04	4.80e-06	2.50e-06
	1.5	1	2	220	NA	2	220	NA	1.20e-03	7.21e-06	3.70e-06
Mixing/loading liquids for aerial application (2)	1.0	350	<1	60	110	<1	60	110	6.90e-03/ 1.40e-02	4.20e-05/ 8.40e-05	2.20e-05/ 4.40e-05
Mixing/loading liquids for hand	1.0	5	25	2615	NA	25	2615	NA	9.80e-05	6.00e-07	NA
gun sprayer (3)	1.5		15	1745	NA	15	1745	NA	1.50e-04	9.00e-07	NA
					Applicator						
Applying liquids with a groundboom sprayer (4)	1.0	80	270	NA	NA	270	NA	NA	1.0e-05/ 2.0e-05	6.50e-06/ 1.30e-05	2.90e-06/ 5.80e-05
	1.0	40	535	NA	NA	535	NA	NA	5.10e-06	3.10e-06	1.40e-06
	1.5		360	NA	NA	380	NA	NA	7.70e-06	4.70e-06	2.10e-06
Applying liquids with a fixed- wing aircraft (5)	1.0	350	See Eng. .Control	See Eng. Control	165	See Eng. Control	See Eng. Control	165	See Eng. Control	See Eng. Control	1.30e-05/ 2.60e-05
Applying liquids with a hand gun	1.0	5	See PPE	205	NA	See PPE	205	NA	See PPE	1.90e-05	NF
sprayer (6)	1.5		See PPE	135	NA	See PPE	135	NA	See PPE	2.90e-05	NF
					Flagger						
Flagging for liquid application (7)	1.0	350	85	NF	760	85	NF	760	9.50e-05/ 1.90e-04	NF	1.90e-06/ 3.80e-06

Baseline dermal exposure scenarios includes long pants, long shirts and no gloves. Baseline inhalation exposure represents no respirator

Additional dermal PPE for scenarios 1, 3 and 6 includes long pants, long shirts and gloves and for scenario 2 includes long pants, long shirts, gloves and coverall. additional inhalation PPE for senario 2 includes organic vapourt respirator (10-fold PF).

Engineering Controls dermal exposure value represents scenario 2 enclosed mixing and loading, scenario 5 Enclosed cockpits and scenario 7 enclosed cab with single layer clothes, no gloves Target MOEs for all the above scenarios are 100.

Two exposure frequencies were used for wheat and barley in the calculations, the first represented the maximum number of applications per site per year to represent private use (10 days), and the second frequency applied a factor of 2 to the first frequency to represent commercial handlers making multiple applications per site per year (20 days) For golf courses 10 days per year.

Maximum PPE (coveralls and organic vapor respirator) were used for cancer assessment.

3.0 POSTAPPLICATION EXPOSURES

Occupational Postapplication Exposure Scenarios

No chemical-specific postapplication human reentry or transferable residue data were submitted in support of the reregistration of diclofop-methyl. Therefore, a surrogate postapplication exposure assessment was conducted to determine potential risks for the representative scenarios. EPA has determined that there are potential postapplication exposures to occupational workers in the following scenarios:

- mowing/maintaining golf course turfgrass; and
- Scouting of wheat and barley field

Harvesting wheat and barley is fully mechanized and there is a low potential for exposure. Fully Mechanized is defined as activities that eliminates the potential of pesticide exposure by physically separating the worker from anything that has been treated with the pesticide to which the restricted-entry interval applies, including, but not limited to, soil, water, air, or surfaces of plants. **These mechanized processes must meet the criteria described in the Worker Protection Standard for entry during an REI for activities with "No Contact."** Examples of "no contact" mechanical processes include harvesting small grains or other crops using combines with closed cabs and cultivating crops (mechanical weed control) with closed cab tractors. Note that if, as is typical, these activities raise significant dust, the closed cab must provide respiratory protection to prevent inhalation exposure. Exposure data for these activities are not required because the triggers for conditional data requirements under 40 CFR §158.390 are not met.

If the workers must exit the closed cab while in the treated area (e.g., to unclog equipment), then they are considered to have potentially come into contact with treated surfaces. During an REI, the workers exiting the cab may use the Worker Protection Standard §170.112 *Exception for short-term activities*, which allows entry into treated areas for a maximum of one hour per day to perform tasks (other than hand labor tasks), as long as early-entry personal protective equipment is worn and the other early-entry requirements are met (i.e., training, decontamination sites, labeling instructions, etc.). However, it should be noted that the early-entry PPE is established for dermal protection only and presumes that pesticide residues have settled out of the air. If the mechanical activity has caused dusts that contain residues to become airborne, the exiting worker will not have respiratory protections, since early-entry PPE does not include a respirator.

3.1 Postapplication Exposures and Assumptions

The assumptions used in the calculations for occupational postapplication risks include:

• The dislodgeable foliar residue values are assumed to be 20 percent of the application rate at day 0 with a 10 percent daily dissipation rate for ornamental applications, and 5 percent of the application rate at day 0 for turfgrass application (the 5 percent rate for turfgrass is the high end of the values observed in Hurto and Prinster, 1993, Goh et al., 1986, and Cowell et al., 1993, additionally this value is consistent with

proprietary data submissions);

- Transfer coefficients (T_c) are assumed to be:
 - -- 500 cm²/hour for mowing/maintaining golf course turf;
 - -- 100 cm²/hour for scouting of wheat and barley.
- Daily exposure is assumed to occur for 8 hours per day for mowing and maintenance of golf course turf, and scouting of wheat and barley.
- The average body weight of 70 kg is used, representing a typical adult.
- Exposure frequency is estimated to be 4 days/year for golf course mowing (assuming diclofop-methyl applied 4 times a year and after first mowing minimal amount of residue exists), and 10 days/year for wheat and barley scouting..
- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years.
- The Q1* used in the cancer assessment is 2.3 E-1 mg/kg/day¹.

3.2 Non-Occupational Post-Application Exposure and Risks

Non-occupational exposure to diclofop-methyl is most likely to occur on a golf course, where it may be applied throughout the year and within a few hours of public usage. The emulsified product is applied by groundboom sprayer and high pressure hanwand. It is most likely that children (over 6 years old) would be exposed on golf courses, therefore the possibility of the exposure of children (most likely accompanying adult golfers) must be entertained. However since the ratio of body weight to surface area of adults is the same as children, therefore it can be assumed that non-occupational risks to adult golfers could be representative of children. The SOP for Residential Exposure Assessments that was completed in December, 1997 contains guidance for considering children's exposure to treated turf.

The assumptions used in the calculations for non- occupational postapplication risks include:

- The dislodgeable foliar residue values are assumed to be 5 percent of the application rate at day 0 for turfgrass application (the 5 percent rate for turfgrass is the high end of the values observed in Hurto and Prinster, 1993, Goh et al., 1986, and Cowell et al., 1993, additionally this value is consistent with proprietary data submissions);
- Transfer coefficients (T_c) are assumed to be:
 - -- 500 cm²/hour for golf course players;
- Daily exposure is assumed to occur for 4 hours per day for golf course players⁴;.
- The average body weight of 70 kg is used, representing a typical adult.

- Exposure frequency is estimated to be, 18 times a year whoever since diclofop-methyl is applied 4 times a year and the residue after mowing is minimal, therefore estimated frequency to highest residue level is 2 days /year for golf player⁵
- Exposure duration is assumed to be 50 years for golf course players.
- Lifetime is assumed to be 70 years.
- The Q1* used in the cancer assessment is 2.3 E-1 mg/kg/day⁻¹.

3.3 Postapplication Exposure and Risk Estimates

The postapplication occupational risks from diclofop-methyl has been assessed using surrogate regression data. The DFR values are derived from the application rate assuming an estimated 20 percent of the rate applied as initial dislodge able residues for wheat and barley assessment and 5 percent for turfgrass application, and an estimated 10 percent dissipation rate per day. The equations used for the calculations are presented below.

Dislodgeable foliar residues (DFRs) were calculated as follows:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) x\ CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) x\ F\ x\ (1\ -\ DR)^t$$

Where:

AR = application rate

 $CF = \text{conversion factor is } 11.2 \text{ lb per cm}^2/\text{lb ai per acre}$

F = fraction retained on foliage

DR = daily dissipation rate (10 percent per day)

t = days after treatment

Daily Doses were calculated as follows:

$$Dose~(mg/kg/d)~=~\frac{(DFR~(\mu g/cm^2)~x~Tc~(cm^2/hr)~x~CF\left(\frac{1~mg}{1,000~\mu g}\right)~x~Abs~x~ED~(hrs/day))}{BW}$$

Where:

DFR = daily DFR, as calculated above for the assumed average reentry day

Tc = transfer coefficient;

CF = conversion factor (i.e., $1 \text{ mg/1,000 } \mu\text{g}$)

Abs = dermal absorption is 100 %, since a dermal endpoint is used

ED = exposure duration; 8 hours worked per day

BW = body weight (70 kg)

MOEs were calculated as follows:

$$MOE = \frac{NOAEL (mg/kg/day)}{Dose (mg/kg/day)}$$

Where:

NOAEL = 5 mg/kg/day

Dose = calculated absorbed dermal dose

Table 5 presents the MOEs for the four scenarios identified with concern for potential postapplication occupational exposure.

3.3.1 Summary of Postapplication Risk

The target dermal MOE is 100 for diclofop-methyl. The results of the postapplication assessment are presented in table 5 and are summarized below:

- Diclofop-methyl MOEs equal or exceed 100 for entry by golf course workers to mow and maintain the turfgrass is acceptable on day of application as soon as the grass is dry. (1.0-1.5 lb ai/acre)
- Diclofop-methyl MOEs equal or exceed 100 for scouting associated with wheat and barley on the day of application. (1.0 lb ai/acre)
- Diclofop-methyl MOEs equal or exceed 100 for entry by golf course player is acceptable on day of application as soon as the grass is dry. (1.0-1.5 lb ai/acre)

REIs have been estimated using the short- and intermediate-term endpoints. Additionally, the cancer endpoint was used to estimate REIs. HED's target range for cancer probabilities are 1E-4 to 1E-6 for occupational, and1E-6 for golfers assessments. Historically, setting REIs on cancer endpoints has been difficult because of the need for lifetime use assumptions. To estimate the LADD (Life time Average Daily Dose) the typical application rate, the number of days worked per year, and the number of years one would be exposed during a working lifetime are needed. Each one of these variables are depenent upon many factors. For example, the number of days worked per year must correspond to the days worked when the pesticide of concern has been applied. Additionally, the residue dissipation over the work interval should be estimated. Without an estimate for residue dissipation one needs to assume (unrealistically) that the worker travels from one treated field to another so that the highest residue value is always found. In the case of diclofop-methyl, a screening estimate was developed because lifetime use data are not available. The screening level estimate assumed: (1) that scouts would be exposed for 10 days, golf course workers 4 days and golf course player 2 days a year; (2) no residue dissipation; and (3) a worker would be exposed for 35 years (50 years for golfers). Based on these assumptions, the cancer probabilities on the day the REIs were estimated, ranged from 2.3E-5 to 2.2E-6. .

3.3.2 Postapplication Data Gaps and Uncertainties

The following data gaps or uncertainties were associated with this assessment:

- No chemical-specific exposure or transferable residue data were submitted. As a result, all analyses were completed using surrogate data from sources and assumptions related to the behavior and environmental fate of the chemical in the environment (e.g., dissipation of transferable residues).
- Factors used to calculate postapplication risks (e.g., hours exposure per day) are often based on the best professional judgment due to a lack of pertinent data.

Table 5. Diclofop-methyl Surrogate Occupational Postapplication Assessment for Treatment to wheat, barley and Golf Course Turf

Crop	Application- Rate	DATª	DFR (μg/- cm²) ^b	Tra	Mow/Maintain Transfer coefficient =500 cm²/hr				Golfing Transfer Coefficient =500				Scouting for wheat and barley Transfer coefficient = 100 cm ² /hr			
				Dermal Dose (mg/kg/- day) ^c	MOE ^d	LADD ^e	Cancer ^f	Dermal Dose (mg/kg/- day) ^c	MOE ^d	LADD ^e	Cancer ^f	Dermal Dose (mg/kg/- day) ^c	MOE ^d	LADD ^e	Cancer ^f	
golf	1.0	0	0.560	0.0048	155	2.63e-5	6.1e-6	0.0024	310	9.40e-6	2.2e-6	NA	NA	NA	NA	
course turf	1.5	0	0.841	0.0072	105	3.95e-5	9.1e-6	0.0036	210	1.41e-5	3.2e-6	NA	NA	NA	NA	
wheat & barley	1.0	0	2.242	NA	NA	NA	NA	NA	NA	NA	NA	0.2562	195	1.0e-04	2.3e-05	

DAT is "days after treatment."

DFR = Application rate x Conversion factor (lb ai/acre = $11.209 \,\mu\text{g/cm}^2$) x fraction of initial ai retained on foliage (20% for wheat and barley and 5 % for turf)* (1-daily dissipation rate), assuming a daily dissipation of 10%.

Dermal Dose = [DFR(\(\mu g/cm^2\)) x Transfer coefficient (cm^2/hr) x conversion factor (1 mg/1,000 \(\mu g\)) x Exposure duration (8 hours/day except for golfers (4 hours/day)) / body weight (70 kg)]

d MOE = NOAEL (mg/kg/day) / Dermal Dose (mg/kg/day); where NOAEL = 5 mg/kg/day. An MOE of 100 is acceptable.

LADD (mg/kg/day) = Dermal Daily Dose (mg/kg/day) * (Number of days exposure per year) /365 days per year) * years worked/70 year lifetime.

(Number of days exposed for golf course maintenance 4 days per year, number of years exposed for golfing 2 days a year and number of days estimated for scouting 10days per year)

Number of years exposed for golf course maintenance and scouting, 35 years and 50 years for golfers

Cancer Risk = LADD (mg/kg/day) * (Q_1*) , where $Q_1* = 2.30e^{-1}$ (mg/kg/day).

APPENDIX A

SHORT- TERM AND INTERMEDIATE- TERM HANDLER EXPOSURE RISK

TABLES A1 THROUGH A4

Table A1: Occupational Handler Short-term and Intermediate-term Risks from Diclofop- methyl at Baseline

Exposure Scenario (Scenario #)		Dermal - Ba	seline			Inhalation -	Baseline		Total - B	aseline
	Unit Exposure (mg/lb ai) ^a	Daily Dose (mg/kg/day) ^b	Short-term MOE ^c	Intterm MOE ^d	Unit Exposure (µg/lb ai) ^a	Daily Dose (mg/kg/day) ^e	Short-term MOE ^f	Intterm MOE ^g	Short-term MOE ^h	Intterm MOE ⁱ
			Mi	xer/Loader Ex	posure					
Mixing/loading liquids for ground	2.9	3.31e+00	2	2	1.2	1.37e-03	1165	1165	2	2
boom application (1)		1.66e+00	3	3		6.86e-04	2335	2335	3	3
		2.49e+00	2	2		1.03e-03	1555	1555	2	2
Mixing/loading liquids for aerial application (2)		1.45e+01	<1	<1		6.00e-03	265	265	<1	<1
Mixing/loading liquids for hand		2.07e-01	25	25		8.57e-05	18665	18665	25	25
gun sprayer(3)		3.11e-01	15	15		1.29e-04	12445	12445	15	15
			A	pplicator Exp	osure					
Applying liquids with a ground	0.014	1.60e-02	315	315	0.74	8.46e-04	1890	1890	270	270
boom sprayer (4)		8.00e-03	625	625		4.23e-04	3785	3785	535	535
		1.20e-02	415	415		6.34e-04	2525	2525	360	360
Applying liquids with fix-wing aircraft (5)	NA	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control
Applying liquids with hand gun	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
sprayer (6)		See PPE	See PPE	See PPE		See PPE	See PPE	See PPE	See PPE	See PPE
				Flagger						
Flagging for liquid application (7)	0.011	5.50e-02	90	90	0.35	1.75e-03	915	915	85	85

Baseline dermal unit exposure scenarios includes long pants, long shirts and no gloves. Baseline inhalation unit exposure represents no respirator.

Table A2: Occupational Handler Short-term and Intermediate-term Risks from Diclofop- methyl with additional PPE

Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg). Short-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day). Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).

Short-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Intermediate-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Total Short-term MOE = 1/((1/Short-term Dermal MOE) + (1/Short-term Inhalation MOE)).

Total Intermediate-term MOE = 1/ ((1/ Intermediate-term Dermal MOE) + (1/ Intermediate-term Inhalation MOE)).

Exposure Scenario (Scenario #)		Dermal - Addit	tional PPE			Inhalation - Ad	ditional PPE		Total - Addi	tional PPE
	Unit Exposure (mg/lb ai) ^a	Daily Dose (mg/kg/day) ^b	Short-term MOE ^c	Intterm MOE ^d	Unit Exposure (µg/lb ai) ^a	Daily Dose (mg/kg/day) ^e	Short-term MOE ^f	Intterm MOE ^g	Short-term MOE ^h	Intterm MOE ⁱ
			Mix	xer/Loader Exp	oosure					
Mixing/loading liquids for ground	0.023	2.63e-02	190	190	1.2	1.37-03	1165	1165	165	165
boom application (1)		1.31e-02	380	380		6.86e-04	2335	2335	325	325
		1.97e-02	255	255		1.03e-03	1555	1555	220	220
Mixing/loading liquids for aerial application (2)	0.017	8.50e-02	60	60	0.12	6.00e-04	2665	2665	60	60
Mixing/loading liquids for hand	0.023	1.64e-03	3045	3045	1.2	8.57e-05	18665	18665	2615	2615
gun sprayer application (3)		2.46e-03	2030	2030		1.29e-04	12445	12445	1745	1745
			A	pplicator Expo	sure					
Applying liquids with a ground	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
boom sprayer (4)		NA	NA	NA	NA	NA	NA	NA	NA	NA
		NA	NA	NA	NA	NA	NA	NA	NA	NA
Applying liquids with fixed-wing aircraft (5)	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control	See Eng. Control
Applying liquid with hand gun	0.34	2.43e-02	205	205	1.4	1.00e-04	16000	16000	205	205
sprayer (6)		3.64e-02	135	135		1.50e-04	10665	10665	135	135
				Flagger						
Flagging for liquid application (7)	NF	NF	NF	NF	NF	NF	NF	NF	NF	NF

Additional dermal PPE for scenarios 1, 3 and 6 includes long pants, long shirts and gloves Additional dermal PPE for scenario 2 includes long pants, long shirts, gloves and coverall additional inhalation PPE for scenario 2 includes organic vapor respirator (10fold PF).

TableA3: Occupational Handler Short-term and Intermediate-term Risks from Diclofop- Methyl with Engineering Controls

Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).

Short-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).

Short-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Intermediate-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Total Short-term MOE = 1/((1/Short-term Dermal MOE) + (1/Short-term Inhalation MOE)).

Total Intermediate-term MOE = 1/ ((1/ Intermediate-term Dermal MOE) + (1/ Intermediate-term Inhalation MOE)).

Exposure Scenario (Scenario #)		Dermal - Eng.	Controls			Inhalation -Eng	. Controls		Total -Eng	g. Controls
	Unit Exposure (mg/lb ai) ^a	Daily Dose (mg/kg/day) ^b	Short-term MOE ^c	Intterm MOE ^d	Unit Exposure (µg/lb ai)ª	Daily Dose (mg/kg/day) ^e	Short-term MOE ^f	Intterm MOE ^g	Short-term MOE ^h	Intterm MOE ⁱ
			I	Mixer/Loader	Exposure					
Mixing/loading liquids for	0.0086	NA	NA	NA	NA	NA	NA	NA	NA	NA
ground boom application (1)		NA	NA	NA		NA	NA	NA	NA	NA
		NA	NA	NA		NA	NA	NA	NA	NA
Mixing/loading liquids for aerial application (2)		4.30e-02	115	115	0.12	6.00e-04	2665	2665	110	110
Mixing/loading liquids for hand		NA	NA	NA	NA	NA	NA	NA	NA	NA
gun sprayer application (3)		NA	NA	NA		NA	NA	NA	NA	NA
				Applicator E	xposure					
Applying liquids with a ground	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
boom sprayer (4)		NA	NA	NA		NA	NA	NA	NA	NA
		NA	NA	NA		NA	NA	NA	NA	NA
Applying liquids with fixed- wing aircraft (5)	0.0050	2.50e-02	200	200	0.35	1.75e-03	915	915	165	165
Applying liquids with hand gun	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
sprayer (6)		NA	NA	NA		NA	NA	NA	NA	NA
			•	Flagge	er					
Flagging for liquid application(7)	0.00022	1.10e-03	4545	4545	0.35	1.75e-03	915	915	760	760

Engineering Controls dermal unit exposure value represents scenario 2 enclosed mixing and loading (organic vapor respirator), scenario 5 Enclosed cockpits and scenario 7 enclosed cab with single layer clothes, no gloves

Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).

Short-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

Intermediate-term Dermal MOE = NOAEL (5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).

Short-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Intermediate-term Inhalation MOE = NOAEL (1.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

Total Short-term MOE = 1/((1/Short-term Dermal MOE) + (1/Short-term Inhalation MOE)).

Total Intermediate-term MOE = 1/ ((1/ Intermediate-term Dermal MOE) + (1/ Intermediate-term Inhalation MOE)).

Exposure Scenario #	Data Source	Standard ^a assumptions (8-hr work day)	Comments ^b
			Mixer/Loader Exposure
Mixing/loading liquid formulations(1,2,3)	PHED V1.1	5 acres for hand gun sprayer 80 acres for groundboom (wheat and barley) 40 acres for groundboom sprayer (golf courses) 350 acres for fixed-wing-aircraft	Baseline: Hand, dermal, and inhalation data are AB grades. Hand = 72 to 122 replicates; dermal = 53 replicates; and inhalation = 85 replicates. High confidence in hand/dermal and inhalation data. PPE: The same dermal data are used as for the baseline coupled with additional use of chemical resistance gloves. Hand data are AB grades, with 59 replicates. High confidence in hand/dermal data. Eng. Control: Engineering Controls::Hands, dermal, and inhalation = AB grades. Hands = 31 replicates; Dermal= 16 to 22; and Inhalation = 27 replicates. High confidence in hands/dermal, and inhalation data. No protection factor was needed to define the unit exposure value. Engineering controls based on closed mixing/loading.
			Applicator Exposure
Applying liquid with a groundboom sprayer (4)	PHED V1.1	80 acres for wheat and barley 40 acres for golf course	Baseline: Hand, dermal, and inhalation data are AB grades. Hand = 29 replicates; dermal = 23 to 42 replicates; and inhalation = 22 replicates. High confidence in hand/dermal and inhalation data.
Applying liquids with fixed- wing aircraft (5)	PHED V1.1	350 acres for wheat and barley	Eng. Control: The same dermal data are used as for the baseline, Dermal replicates = 24 to 48, ABC grades. Hand replicates = 7, All Grades. Low Confidence run due to inadequate hand number and poor grade quality.
Applying liquids with hand gun sprayer (6)	PHED V1.1	5 acres for golf courses	PPE: Hand, dermal data are C grades, with 14 replicates. Low confidence in hand/dermal and inhalation data.
Flagging for liquid application(7)	PHED V1.1	350 acres	Baseline: Hands, dermal and inhalation acceptable grades. Hands = 30 replicates; dermal = 18 to 28 replicates; and inhalation = 28 replicates. High confidence in dermal, hands, and inhalation data. PPE: Not feasable Engineering Controls:98% protection added to baseline for a flagger in an enclosed cab truck.

Standard Assumptions based on an 8-hour work day as estimated by HED. BEAD data were not available.

All handler exposure assessments in this document are based on the "Best Available" data as defined by HED SOP for meeting Subdivision U Guidelines. Best available grades are assigned to data as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows: High= grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low= grades A, B, C, D and E or any combination of grades with less than 15 replicates

APPENDIX B

OCCUPATIONAL HANDLER INTERMEDIATE AND LONG -TERM CANCER (\mathbf{Q}^*) RISKS

TABLE B

Exposure Scenario (Scenario #)	Total Baseline Daily Dose (mg/kg/day) ^{ca}	Baseline Daily LADD ^b	Baseline Risk ^c	PPE Total Daily Dose ^d	PPE LADD ^e	PPE RISK ^f	Eng.Cont Total Daily Dose ^g	Eng.Cont LADD ^h	Eng.Control Risk ⁱ
				Mixer/Loader Exp	osure				
Mixing/loading liquids for ground boom application	4.99e-01	6.80e-03/ 1.36e-02	1.60e-03/ 3.20e-03	3.03e-03	4.18e-05/ 8.36e-05	9.61e-06/ 1.92e-05	1.60e-03	2.10e-05/ 4.20e-05	4.90e-06/ 9.80e-06
,	2.49e-01	3.40e-03	7.90e-04	1.53.e-03	2.10e-05	4.80e-06	7.90e-04	1.10e-05	2.50e-06
	3.74e-01	5.10e-03	1.20e-03	2.30e-03	3.14e-05	7.21e-06	1.20e-03	1.60e-05	3.70e-06
Mixing/loading liquids for aerial application (2)	2.18e+00	3.00e-02/ 6.00e-02	6.90e-03/ 1.40e-02	1.34e-02	1.80-04/ 3.60e-04	4.20e-05/ 8.40e-05	6.90e-03	9.40e-05/ 1.90e-04	2.20e-05/ 4.40e-05
Mixing/loading liquids for hand gun sprayer application (3)	3.10e-02	4.30e-04	9.80e-05	1.90e-04	2.60e-06	6.00e-07	NA	NA	NA
sprayer application (3)	4.70e-02	6.40e-04	1.50e-04	2.90e-04	3.90e-06	9.00e-07	NA	NA	NA
				Applicator Exposu	re				
Applying liquids with a ground boom sprayer (4)	3.00e-03	4.40e-05/ 8.80e-05	1.0e-05/ 2.0e-05	2.00e-03	2.70e-05/ 5.40e-05	6.50e-06/ 1.30e-05	9.10e-04	1.20e-05/ 2.40e-05	2.90e-06/ 5.80e-05
	2.00e-03	2.20e-05	5.10e-06	9.90e-04	1.30e-05	3.10e-06	4.50e-04	6.20e-06	1.40e-06
	2.00e-03	3.30e-05	7.70e-06	1.50e-03	2.00e-05	4.70e-06	6.80e-04	9.30e-06	2.10e-06
Applying liquids with fixed-wing - Aircraft (5)	See. Eng Control	See. Eng Control	See. Eng Control	See. Eng Control	See. Eng Control	See. Eng Control	4.10e-03	5.60e-05/ 1.10e-04	1.30e-05/ 2.60e-05
Applying Liquids with hand gun sprayer (6)	See PPE	See PPE	SeePPE	2.00e-03	8.40e-05	1.90e-05	NF	NF	NF
sprayer (0)	See PPE	See PPE	See PPE	3.10e-04	1.30e-04	2.90e-05	NF	NF	NF
				Flagger				,	1
Flagging for liquid application (7)	1.00e-02	4.10e-04/ 8.20e-04	9.50e-05/ 1.90e-04	NF	NF	NF	2.0e-04	8.20e-06/ 1.60e-05	1.90e-06/ 3.80e-06

Baseline Total Daily Dose = [Baseline Daily Dermal Exposure (mg/day) + Baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).long pants, long shirts and no gloves

Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (Number of days exposed per year applicator) /365 days per year) * 35 years worked/70 year lifetime.

Baseline Total Cancer Risk = Baseline LADD $(mg/kg/day) * (Q_1*)$, where $Q_1* = 2.3e^{-1} (mg/kg/day)$.

d PPE Total Daily Dose = [PPE Daily Dermal Exposure (mg/day) + baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg). (coveralls and organic vapor respirator)

PPE LADD (mg/kg/day) = PPE Total Daily Dose (mg/kg/day) * (Number of days exposed per year) /365 days per year) * 35 years worked/70 year lifetime.

PPE Total Cancer Risk = PPE LADD (mg/kg/day) * (Q_1*) , where $Q_1* = 2.3e^{-1}$ (mg/kg/day).

Eng. Control Total Daily Dose = [Eng. Control Daily Dermal Exposure (mg/day) + baseline Daily Inhalation Exposure (mg/day)]/Body Weight (70 kg).

Eng. Control LADD (mg/kg/day) = Eng. control Total Daily Dose (mg/kg/day) * (Number of days exposed per year) /365 days per year) * 35 years worked/70 year lifetime.

Eng. Control Total Cancer Risk = Eng. Control LADD (mg/kg/day) * (Q_1^*) , where $Q_1^* = 2.3e^{-1}$ (mg/kg/day).

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